IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	MDL No. 1:13-md-2419-FDS
This Document Relates to: All Cases	)	Judge Rya W. Zobel

DEFENDANT AMERIDOSE LLC'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR PROTECTIVE ORDER AND MOTION TO QUASH THE DEPOSITION NOTICE TO AMERIDOSE LLC

Pursuant to Rule 26(c) of the Federal Rules of Civil Procedure, Ameridose LLC moves for entry of an Order quashing the deposition notice served on Ameridose LLC and forbidding The Saint Thomas Entities ("STEs") from taking the deposition of Ameridose LLC.

I. INTRODUCTION

Federal Rule of Civil Procedure 30(b)(6) permits a party to issue a Notice of Deposition to an organization requesting that it produce a person able to testify about specific topics. Under Rule 30(b)(6), the organization must then "designate one or more officers, directors, or managing agents, or designate other persons . . . ." to testify regarding the requested topics. In their 30(b)(6) Notice, the STEs seek testimony from Ameridose's designated corporate witness(es) regarding 16 topics, focusing primarily on Ameridose's purported relationships with the New England Compounding Pharmacy, Inc. ("NECC") and other companies, as well as NECC's own clean room, compounding, and marketing practices. *See* Notice to Ameridose of 30(b)(6) Deposition, NECC MDL Doc. 1809.

The STEs' request to depose Ameridose regarding these topics should be denied for several reasons. *First*, Ameridose's owners and managers are involved in parallel criminal proceedings based on the same events at issue here. As a result, each of them intends to invoke their Fifth Amendment rights against self-incrimination and will refuse to testify or be subject to an examination under Rule 30(b)(6). *Second*, none of the people who might be designated under Rule 30(b)(6) will consent to testify on Ameridose's behalf. *Third*, none of the information sought in the STEs' 30(b)(6) Notice is relevant to any claim asserted against or defense raised by the STEs. As the STEs are fully aware – based on pleadings and motions filed in this litigation as well as Ameridose's discovery responses – at no time did Ameridose manufacture, compound, dispense, test, sell, or distribute MPA. Ameridose could not be liable in tort to Plaintiffs and taking discovery against it cannot be pertinent to the STEs' comparative fault defenses. Nor did the STEs actually buy and inject MPA from NECC. Therefore, the information sought is beyond the scope of the limited exception to the discovery stay still in effect in this litigation. *See* October 9, 2014 Order, NECC MDL Doc. 1482. *Finally*, the cost and burden of taking discovery from Ameridose far outweighs its utility.

This Court should therefore issue an order quashing the STEs' 30(b)(6) Notice as to Ameridose and enter a Protective Order protecting Ameridose from having to designate and present any Rule 30(b)(6) representatives for deposition.

II. ARGUMENT

A. Ameridose's Owners, Managers, and Agents Intend to Invoke Their Fifth Amendment Rights Against Self-Incrimination and Therefore Cannot Be Compelled to Testify on Ameridose's Behalf.

At all times relevant to these proceedings, Ameridose LLC had seven owners, managers, and/or agents who could theoretically qualify as 30(b)(6) witnesses. Based upon a reasonable investigation it is apparent that they intend to invoke their Fifth Amendment privilege against self-incrimination, refusing to answer any questions at deposition. *See, e.g.,* Affidavit of M.P. Moriarty at ¶¶ 3-5, attached as Exhibit A; *see also* Invoking Defendants' Motion to Quash and Motion for Protective Order, NECC MDL Doc. 1823.[1] In fact, some of these individuals have already responded to the STEs' requests for admission, interrogatories, and requests for production by invoking their Fifth Amendment privilege, and have filed their own motions for protective order in response to deposition notices issued to them individually.

This Court cannot compel these same individuals to appear as 30(b)(6) witnesses if they intend to assert their Fifth Amendment privilege. *See, e.g.*, *City of Chicago v. Reliable Truck Parts Co., Inc.*, 768 F. Supp. 642, 646-47 (N.D. Ill. 1991) ("This court cannot compel individuals to testify in their corporate capacity if they otherwise have an individual privilege that can properly be invoked."); *City of Chicago, III v. Wolf*, No. 91 C 8161, 1993 WL 177020, *1 (N.D. Ill. May 21, 1993); *see also* Invoking Defendants' Motion to Quash and Motion for Protective Order, NECC MDL Doc. 1823. It is undisputed that these individuals have the right to invoke their Fifth Amendment rights against self-incrimination and not be subject to sanctions or contempt for failing to appear to testify on Ameridose's behalf in response to the STEs' 30(b)(6)

[1] Ameridose filed a Joinder to the Invoking Defendants' Motion to Quash on May 5, 2015 (NECC MDL Doc. 1824).

Notice. *See Martinez v. Majestic Farms, Inc.*, No. 05-60833-CIV, 2008 WL 239164, *3 (M.D. Fla. Jan. 12, 2010).

Importantly, the STEs cannot use the individuals' invocation of their Fifth Amendment privilege to create an inference that contradicts a known fact: that Ameridose did not manufacture, compound, dispense, test, sell, or distribute MPA. Because any potentially qualified 30(b)(6) witness will undoubtedly assert their Fifth Amendment privilege, this Court should not compel them to testify at deposition.

B. There Are No Other Persons Who Will Consent To Testify On Ameridose's Behalf.

Rule 30(b)(6) expressly states that the organization named in the deposition notice must designate – if not officers, directors or managing agents – "other persons **who consent to testify**" on the corporate entity's behalf. Fed. R. Civ. P. 30(b)(6) (emphasis added). Not only will the owners of Ameridose refuse to accept the designation of a 30(b)(6) witness, there is no "other person" presently associated with Ameridose who has sufficient knowledge of the requested deposition topics and who will consent to testify. (*See* Affidavit of M.P. Moriarty at ¶¶ 3-5.) Further, Ameridose has no control over former employees or agents who may be designated as "other persons," these persons will not provide consent to be deposed, and therefore Ameridose is not required to designate them under Rule 30(b)(6). *See, e.g.*, *S.E.C. v. Banc de Binary*, No. 2:13-cv-993, 2014 WL 1030862, n.10 (D. Nev. March 14, 2014) ("Because Mr. Katz is no longer associated with Banc de Binary . . . he is no longer subject to being deposed under Rule 30(b)(6) **unless he consents**.") (emphasis added). Nor can Ameridose be compelled to retain and produce a person not previously associated with the company simply so that person can respond to the STEs' 30(b)(6) Notice. It does not have documents available to provide

information on the topics listed in the STEs' 30(b)(6) Notice, such that an unaffiliated person could "testify about information known or reasonably available to the organization." Fed. R. Civ. P. 30(b)(6). Because of the nature of these proceedings, the settlement agreement reached by the Affiliated Defendants, and the discovery stay in effect for much of this litigation, Ameridose has not processed the majority of the company's documents for production. The cost associated with processing and storing these documents is extraordinary and the burden on Ameridose of extensive document discovery and witness preparation is excessive and unwarranted. (*See* Affidavit of M.P. Moriarty at ¶¶ 3-9 and; *see also* Section II.E., *infra*.)

In addition, Ameridose should not be compelled to retain an unaffiliated person for deposition because it cannot provide that person with information without breaking the owners' and managers' privilege, and it does not have the documents to educate someone. The only two people still associated with Ameridose who have knowledge and information regarding the topics in the 30(b)(6) Notice are the owners and managers who intend to invoke their Fifth Amendment privilege. These individuals are not required to provide information to a newly designated deponent. *Wolf*, 1993 WL 177020 at *2. Importantly, "this court cannot compel the individual defendants who choose to remain silent to respond to inquiries by the 30(b)(6) deponent." *Reliable Truck Parts Co., Inc.*, 768 F. Supp. at 646. "To hold otherwise would require the persons with a Fifth Amendment privilege to provide testimony to the designated deponent." *Wolf*, 1993 WL 1777020 at *2. Since there are no "other persons" who will consent to testify on the subjects identified in the STEs' 30(b)(6) Notice, this Court should quash the deposition notice served on Ameridose.

C. This Court Should Prohibit Any Ameridose Company Witness Depositions Because They Are Beyond the Scope of Rule 26 and the Limited Exception to the Discovery Stay.

Pursuant to the Court's most recent order on discovery, the STEs or other parties are permitted to conduct discovery of Ameridose "only to the extent the discovery is relevant to the prosecution, or defense, of claims against defendants [e.g., the STEs] other than the Estate Parties or the Insider Settling Parties." *See* NECC MDL Doc. 1482. Although the exception to the stay is narrow, the discovery the STEs seek in their 30(b)(6) Notice does not fall within that exception because the discovery cannot support the STEs' claims or defenses.

Under Tennessee law, the STEs have the right to point to an empty chair at trial and claim comparative fault. Here, however, the STEs cannot establish liability (no duty owed and no causation) against Ameridose because Ameridose did not manufacture, compound, dispense, sell, test, or distribute the alleged injurious product. *See Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 405 (6th Cir. 2013); NECC MDL Doc. 1482 (Oct. 9, 2014). The pleadings and discovery already on file in this litigation show that NECC was the sole entity responsible for compounding and dispensing MPA. Nor did Ameridose operate and/or maintain NECC's clean rooms at the time NECC compounded and dispensed the MPA. Under Tennessee law, a defendant in a negligence claim can only be liable for the portion of damages caused by its own negligence. *McIntyre v. Balentine*, 833 S.W.2d 52, 58 (Tenn. 1992). Because Ameridose cannot be held liable under Tennessee law, the STEs have no valid claim for comparative fault and should not be permitted to proceed with its 30(b)(6) Notice as to Ameridose.

1. Ameridose was neither the compounder nor dispenser of the MPA at issue in this litigation and therefore cannot be held liable under Tennessee product liability law.

Under the Tennessee Product Liability Act of 1978 ("the Act"), a "manufacturer" or "seller" can be liable for personal or property damage caused by a product if any only if the "product is determined to be in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller." T.C.A. § 29-28-105(a). Under the Act, a "manufacturer" is the "designer, fabricator, producer, compounder, processor or assembler of any product or its component parts." T.C.A. § 29-28-103(4). A "seller" is "any individual or entity engaged in the business of selling a product." T.C.A. § 29-28-102(7). A seller, however, cannot be held liable unless it exercised substantial control over the part of the product that caused the alleged harm, altered or modified the product and that modification or alteration was a "substantial factor" in the alleged harm, or the manufacturer is not subject to service of process in Tennessee. T.C.A. § 29-28-106.

None of the Act's provisions apply to Ameridose in this litigation. The pleadings on file and facts in evidence in this litigation confirm that Ameridose is not the manufacturer, compounder, dispenser or seller of the MPA at issue:

- "Ameridose did not compound MPA. Products distributed by Ameridose did not contribute to the [meningitis] outbreak." Declaration of Chapter 11 Trustee in Support of Confirmation of Second Amended Joint Chapter 11 Plan of NECC, NECC MDL Doc. 1858, p. 16.

- The list of Recalled Products posted on the U.S. Food and Drug Administration's website at the time Ameridose voluntarily recalled its entire product inventory in October 2012 clearly does not include "methylprednisolone acetate" in its inventory. *See* http://www.fda.gov/Safety/Recalls/ucm326349.htm, Press Release Announcing Ameridose Recall, and http://www.fda.gov/drugs/drugsafety/fungalmeningitis/ucm326384.htm, listing of all products recalled by Ameridose.

- In this Court's May 15, 2014 Order on the Trustee's Renewed Motion to Transfer, this Court succinctly stated that "[t]his case involves claims for wrongful death and personal injury arising out of the administration of an injectable steroid, methylprednisolone acetate ("MPA"), manufactured by defendant New England Compounding Pharmacy, Inc. ("NECC")." NECC MDL Doc. 1131, pp. 1-2.

- In Ameridose's responses to the STE's Interrogatories, Requests for Admission, and Requests for Production, Ameridose repeatedly stated it did not manufacture, compound, dispense, test, or distribute the MPA at issue in this litigation. *See* Notice of Service of Discovery Responses, Apr. 14, 2015, NECC MDL Doc. 1774.

- In the STEs' own Memorandum in Support of their Motion for Continuance of Common Issue Fact Discovery, the entities state that NECC compounded the MPA at issue in this litigation. *See* NECC MDL Doc. 1850, p. 1. Though the STEs take over three pages to list the names of individuals and entities from whom it needs discovery, this pivotal statement appears on the first page of its Memorandum.

- The published medical literature about the outbreak discusses the origins of the MPA. Ameridose is not part of the discussion. See, e.g., *Rachel Smith, et.al.*, *Fungal Infections Associated with Contaminated Methylprednisolone Injections,* NEJM, 369; 17, pgs. 1598-1609 (2013), attached as Exhibit F to NECC MDL Doc. 1090. To date, our research discloses at least thirteen other scientific articles about the fungal meningitis outbreak. They frequently refer to the MPA coming from "a single compounding pharmacy." None of the articles even mention Ameridose.

- In an October 2012 *New York Times* article, it was noted that: "the FDA even acknowledged its [own] actions as to Ameridose during the post-recall investigations were different than those as to NECC." The article quoted the Director of the FDA's Center for Drug Evaluation and Research as saying that "the Agency is not asking health care providers to track down patients who were given Ameridose products . . . because there have been no reports of problems." *See* Erkan Doc. No. 8, Ex. 1 at att. #18, *N.Y. Times* Oct. 31, 2012.

- Ameridose has represented to this Court, and it holds true today, that there are no pending cases alleging harm from an Ameridose product. *See, e.g.* NECC MDL Docket No. 1090.

Since Ameridose did not manufacture, compound, dispense or distribute MPA, it cannot be held liable under Tennessee law. Therefore, there is no reason that this Court should allow the STEs

to conduct extensive discovery of Ameridose that so clearly falls outside the limited exception to the discovery stay.

2. The STEs never even injected MPA into any patients.

Although at least one individual Saint Thomas Entity (St. Thomas Hospital) was a customer of Ameridose, none of the entities ever purchased or injected into any of their own patients the MPA at issue in this MDL. *See* The STEs' Memo. in Support of their Mot. to Dismiss, NECC MDL Doc. 894, at 3; The STEs' Memo. in Support of Mot. for Continuance of Common Fact Discovery, NECC MDL Doc. 1850, at 1. Plaintiffs' assertion of liability against the STEs stems only from their alleged relationship with the Tennessee Clinic Defendants, entities that actually *did* procure and inject tainted MPA. *See* NECC MDL Doc. 894, at 4. Not only did the STEs neither buy nor inject MPA, the STEs also claim they have no ownership interest in STOPNC and never employed any of the STOPNC defendants accused of wrongdoing. *Id.* So why is it that the STEs – entities that never purchased or injected any of the tainted MPA – require extensive, excessively burdensome fact discovery from Ameridose, an entity the STEs acknowledge never compounded or sold the tainted MPA, the only drug at issue in this litigation? If the STEs never purchased or injected MPA, then their employees could not have relied on any Ameridose or NECC marketing materials, trade booth presentations, regulatory representations, etc., pertinent to the issues in this case. Any discovery obtained from Ameridose will not assist the STEs in defending against claims asserted by the Tennessee Plaintiffs and should therefore be precluded.[2]

[2] To the extent the Tennessee Clinic Defendants ("TCDs") want to piggyback on the STEs' subpoenas, it makes just as little sense to allow discovery to proceed against Ameridose because the TCDs were not even Ameridose customers.

3. Ameridose did not operate or maintain NECC's clean rooms at the time NECC compounded and dispensed MPA and therefore cannot be held liable.

The STEs may suggest liability against Ameridose arising out of clean room design or maintenance. When Ameridose conducted its business operations out of the Framingham, MA facility (2006 – early 2009), it contracted to build, and then operated and contracted to maintain its own clean rooms in its portion of that facility. Ameridose moved its entire business operations to a larger facility in Westborough, MA in early 2009, more than three years before NECC compounded and dispensed the MPA at issue in this litigation.[3] Although Ameridose may have initially contracted with Liberty Industries to design the clean rooms it used in Framingham, it did so to facilitate the manufacture of its own products, not NECC's. Furthermore, NECC was entitled to and may have changed the design of these clean rooms after Ameridose left. What NECC did with those clean rooms after Ameridose moved to Westborough can be discovered from NECC documents or those of the contractors NECC hired to maintain those areas during the three years after Ameridose moved and before NECC compounded and dispensed the MPA at issue.

4. The STEs cannot establish that Ameridose's conduct was the cause of the MPA contamination, meningitis outbreak, or resulting injuries.

An "essential element of any products liability action in Tennessee is that the defect in question proximately caused the plaintiff's injury." T.C.A. § 29-28-105(a); *see also Pride v. Bic Corp.*, 54 F. Supp. 2d 757, 764 (E.D. Tenn. 1998) *aff'd*, 218 F.3d 566 (6th Cir. 2000). This

[3] This information is contained in Ameridose's responses to the STEs' written discovery. *See* Notice of Service of Discovery Responses, Apr. 14, 2015, NECC MDL Doc. 1774.

includes proof of "both proximate cause and cause in fact." *Nye v. Bayer Cropscience, Inc.*, 347 S.W.3d 686, 704 (Tenn. 2011).

Regarding the one product at issue in this litigation – the MPA compounded and dispensed only by NECC – Ameridose did not owe a duty to any of the plaintiffs in this litigation. Under Tennessee product liability law, Ameridose is neither at fault nor liable. T.C.A. § 29-28-106(b). It cannot be either the cause in fact or proximate cause of the Tennessee Plaintiffs' damages, or, this, the STEs, or the Tennessee Clinic Defendants' need for comparative fault. "'Cause in fact'" refers to the cause and effect relationship between the defendant's tortious conduct and the plaintiff's injury and loss." *Id.* at 705. "Thus, cause in fact deals with the 'but for' consequences of an act – i.e., a defendant's conduct is a cause of the event if the event would not have occurred but for that conduct." *Id.* In contrast, proximate cause, or legal cause, concerns a determination of whether legal liability should be imposed where cause in fact has been established. *Id.* at 705 (quoting *Snyder v. LTG Lucttechnische GmbH*, 955 S.W.2d 252, 256 n.6 (Tenn. 1997)).

Under Tennessee law, only a defendant that manufactured a product can be liable for injuries caused by that product – which entirely precludes Ameridose's liability as to Tennessee plaintiffs and the STEs in this litigation. *See Nye*, 347 S.W.2d at 705. Ameridose cannot be actively liable to any Tennessee Plaintiff in this litigation. Further – having never compounded, tested, or distributed the MPA at issue here – it also took no action that can be determined to be the proximate cause of any harm to any Tennessee Plaintiff.

5. There is no basis for the reduction of a verdict based on strict liability claims against Ameridose.

The STEs' discovery goals from Ameridose will not lead to a reduction of any verdict

against the STEs based on strict liability. They are, thus, outside the scope of the exception to the stay.

First, Ameridose can only be held liable under the Tennessee Products Liability Act for its own wrongdoing, and here there is none. To date, the STEs have not made any claim that Ameridose can be held responsible for NECC's actions under any theory including alter ego.[4] Although Ameridose and NECC are not in a parent-subsidiary relationship (they are sister corporations), the law about that subject is useful here. The actions of a parent may only be attributable to a subsidiary in two instances: "(1) when one corporation is acting as an agent for the other or (2) when the corporations are essentially alter egos of each other." *Wells ex rel. Baker v. State*, 435 S.W.3d 734, 756 (Tenn. Ct. App. 2013). The same principles apply to liability between two subsidiaries of the same parent corporation. *See In re U-Haul Intern., Inc.*, 87 S.W.3d 653, 656-57 (Tex. 2002) (acknowledging that sibling-companies are separate and distinct, even if they have the same officers). And some courts have held that there can be no alter ego liability for sister corporations. *Minno v. Pro-Fab, Inc.*, 905 N.E.2d 613, 617 (Ohio 2009) ("Despite the element of common shareholder identity, sister corporations are separate corporations and are unable to exercise control over each other in the manner that a controlling shareholder can. This lack of ability of one corporation to control the conduct of its sister corporation precludes application of the piercing-the-corporate-veil doctrine.").

Second, if the STEs' theory against Ameridose is strict liability in tort or only a derivative theory based on NECC's conduct, Ameridose will be considered to be a "single-share"

[4] According to the STEs' own Motion to Dismiss filed in this Court, mere factual allegations, "even if proven, would not suffice under Tennessee law to pierce the corporate veil." NECC MDL Doc. 894, p. 13. As the STEs have already argued in another context, "[m]ere ownership . . . is not enough to pierce the corporate veil; [n]or is the common name and proximity of facilities." NECC MDL Doc. 894.

with NECC, the primary defendant, for purposes of the comparative fault calculation – precluding a reduction in any verdict against the STEs because of Ameridose's stand-alone conduct. *Owens v. Truckstops of America*, 915 S.W.2d 420, 433 (Tenn. 1996). The fault of all the defendants "is measured by the injury caused by the defective or unreasonably dangerous product." *Id.* Under Tennessee law, any verdict against Ameridose will not reduce a verdict against the STEs for the same injuries as caused by NECC's conduct.

Since Ameridose did not manufacture, test, compound, dispense, or sell the MPA at issue, it would be legally impossible to find Ameridose at fault and NECC not at fault. Based upon the foregoing, even putting Ameridose on a verdict form would be meaningless and likely impermissible in a Tennessee trial. Any discovery obtained from Ameridose is irrelevant to the prosecution, or defense, of claims against the STEs and should not be permitted.

D. The Discovery Sought By The STEs In Their 30(B)(6) Notice Is Not Reasonably Calculated To Lead To Admissible Evidence.

It is axiomatic that discovery must be relevant and reasonably calculated to lead to the discovery of admissible evidence. *See* Fed. R. Civ. P. 26(b)(1). Here, that means evidence must be relevant and reasonably calculated to lead to admissible evidence in a claim that Ameridose, or conceivably NECC, is at fault, so as to reduce the STEs' share of liability. An examination of the STEs' 30(b)(6) Notice demonstrates that the requested documents are beyond the scope of discovery in this litigation as they cannot be used to prove either Ameridose's or NECC's liability.

The STEs request a deponent who can testify about "Ameridose's regulatory history, including without limitation the information contained in the Congressional Report 'FDA's Oversight of NECC and Ameridose: A History Of Missed Opportunities?'" (STEs' 30(b)(6)

Notice, Subject 5). If Ameridose did not manufacture, compound, test, dispense, or distribute the MPA at issue in this litigation, then what is the purpose of their request? It must somehow relate to NECC and NECC's liability.

Assume hypothetically that Ameridose's products were at issue in this MDL. Even if the STEs discover evidence that Ameridose's products were noncompliant with FDA regulations, that evidence is not relevant to the issue of whether Ameridose's products are defective under state tort law. *King v. Danek Med., Inc.*, 37 S.W.3d 429, 442 (Tenn. Ct. App. 2000); *United States v. 789 Cases, More or Less, of Latex Surgeons' Gloves*, 799 F. Supp. 1275, 1285 (D.P.R. 1992); *Howard v. Sulzer Orthopedics, Inc.*, No. 02-CV-0564, 2011 WL 2472594, *6 (N.D. Okla. June 21, 2011) ("Based on the lack of a private cause of action in the FDCA, 'many courts have held plaintiffs cannot seek to enforce it through negligence per se tort actions.'") (citing *Bartlett v. Mut. Pharm. Co., Inc.*, 731 F. Supp. 2d 135, 154 (D.N.H. 2010)); *Krueger v. Johnson & Johnson Prof'l, Inc.*, No. 4:00-cv-10032, 2002 WL 34371190, *5 (S.D. Iowa Sept. 10, 2002) ("[T]estimony [of failure to comply with FDA regulations] does not prove that the . . . device implanted in [plaintiff] was defective, or that it was a proximate cause of his injuries."). Because noncompliance with regulations cannot be used to establish that a product is defective, even the product of the target defendant, the STEs' attempt to obtain this information from Ameridose is improper and should be rejected.

If the regulatory evidence sought by the STEs cannot be used to establish a claim against Ameridose, any attempt to find and use that evidence against NECC is even more attenuated. In other words, even if Ameridose had regulatory problems, they are irrelevant to NECC's liability. This is especially important here where Ameridose did not manufacture, compound, dispense,

test, sell, or distribute the product at issue. *See Verzwyvelt v. St. Paul Fire & Marine Insur.*, 175 F. Supp. 2d 881, 888 (E.D. La. 2001) (holding that evidence of recall involving entirely different product, manufactured at an entirely different manufacturing facility, in different location was not relevant because it would unfairly prejudice defendant, confuse the issue, and mislead the jury).

The exact same analysis applies, for example, to other requests in the STEs' 30(b)(6) Notice, such as:

- Ameridose's organizational structure and identification of its owners, executives, employees, managers, and other representatives (STEs' 30(b)(6) Notice, Subject Nos. 2-3);
- Ameridose's policies and procedures (STEs' 30(b)(6) Notice, Subject No. 4);
- Customer communications (STEs' 30(b)(6) Notice, Subject No. 6);
- Communications with NECC and other affiliated companies (STEs' 30(b)(6) Notice, Subject No. 8); and
- General information regarding NECC and its business operations (STEs' 30(b)(6) Notice, Subject Nos. 9, 10, 13, 15).

To meet Rule 26's relevance requirement, these topics must be offered to show either Ameridose's or NECC's liability. They are not. Quite obviously, information regarding Ameridose's corporate structure and policies and procedures are not relevant to prove Ameridose's liability and cannot be used to prove fault against NECC. Similarly, information regarding Ameridose's communications with its customers, NECC, or any of the other purportedly affiliated companies is not relevant because the STEs never purchased MPA or

injected MPA into any of their patients and because the TCDs were not even customers of Ameridose. And since the STEs never purchased MPA or injected MPA into any of their patients, any information from Ameridose regarding NECC and its business operations is also not relevant. Furthermore, the Tennessee Defendants could not have relied on Ameridose for information about MPA or NECC's clean rooms. (*See* STEs' 30(b)(6) Notice, Subject Nos. 7, 11, 12). Even if they did, they would remain one "single share" on a verdict form.

Simply put, the STEs' attempt to obtain documents from Ameridose is nothing more than a burdensome and expensive fishing expedition that will neither lead to relevant nor admissible evidence. That puts the requested discovery outside the scope of the Federal Rules, and much further outside the scope of the limited exception to the stay on discovery. Therefore, the discovery should not be permitted.

E. The Cost Of Discovery Against Ameridose Would Be Significant And Unduly Burdensome.

Rule 26 (c)(1) permits a court to issue an order to protect a party against whom discovery is sought from undue burden or expense, including forbidding the discovery. Rule 26(b)(2)(C) specifically requires a court to:

> Limit the frequency or extent of discovery . . . if it determines that . . . the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the action, and the importance of the discovery in resolving the issues.

Consistent with this Rule, courts have routinely granted orders protecting parties from undue burden and expense and have even shifted costs to the requesting party when the burden and expense is significant, as in the case here. *See*, *e.g.*, *Oppenheimer Fund v. Sanders*, 437 U.S. 340, 358 (1978) (noting that Rule 26(c) permits courts to grant orders protecting parties from

"undue burden and expense"); *Zubulake v. UBS Warburg, LLC*, 217 F.R.D., 309, 322 (S.D.N.Y. 2003) (outlining factors courts should consider when balancing the cost and burden of discovery under Rule 26(c)); *Rowe v. Entertainment, Inc. v. The Williams Morris Agency, Inc.*, 205 F.R.D. 421, 429 (S.D.N.Y. 2002) (ordering cost-shifting in e-discovery dispute). Without the protection of Rule 26(c), parties will always, if left to their own devices, endlessly fish for information, no matter how costly and no matter how unlikely the fishing is to yield results actually helpful to the administration of justice.

Here, the affidavit of Matthew Moriarty makes clear why each of the above factors heavily weighs in favor of Ameridose. First, the affidavit sets forth the costs of just certain document production issues. (*See* Affidavit of M.P. Moriarty at ¶ 9). The parties, having settled and soon to receive releases and dismissals, should not be required to utilize unnecessary resources and expend over $1,000,000 to engage in document discovery. This is particularly true in a case in which the discovery target is not liable in products liability or a derivative theory. Second, and as previously discussed, any discovery sought from Ameridose has no benefit or importance in resolving issues presented in this litigation. That is because Ameridose did not manufacture, compound, dispense, test, sell, or distribute the MPA at issue in this litigation. Because the burden and expense of the STEs proposed discovery significantly outweighs its benefit, this Court should issue an Order forbidding the STEs' discovery against Ameridose.

III. CONCLUSION

The STEs have before them an entity that undoubtedly compounded MPA - NECC. The legal and scientific record is clear: certain lots of MPA, compounded by NECC in 2012, were contaminated. Making the legal case of liability is simple, and presumably the Plaintiffs and Tennessee Clinic Defendants have doctors standing in line to testify about the causal link

between MPA injections and harm to individuals. Yet, the STEs want to make discovery against Ameridose, which will be costly, protracted and low yield. There is simply no legal or factual basis for the cost given that there is no evidence that Ameridose compounded the MPA at issue. Therefore this Court should issue an Order quashing the deposition notice served on Ameridose LLC and forbidding the STEs from taking the deposition of Ameridose LLC.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 22, 2015, a copy of the foregoing **Defendant Ameridose LLC's Memorandum in Support of its Motion for Protective Order and Motion to Quash the Deposition Notice to Ameridose LLC** was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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